



Panel 2: Solutions from the EU
and the Member States:
Which solutions from regulatory perspective exists?
- Which are additionally needed?

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ABDA, MEDICINES SHORTAGES: GIVING UP?
FINDING SOLUTIONS! 01/12/2020



Presentation focused on:

1. COVID-19 Health Response Package:
Proposal for a Reinforced EMA Role
2. Pharmaceutical Strategy
for Europe
3. “Future-proofing pharmaceutical legislation
— study on medicine shortages”

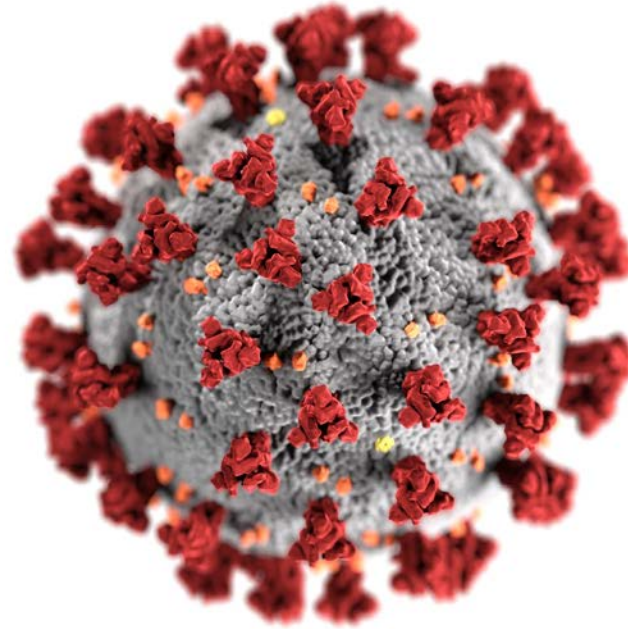


COVID-19 Health Response Package: Proposal for a Reinforced EMA Role

Aspects highlighted by COVID-19

**Crisis
management and
preparedness**

**Dependency
on APIs**



Shortages

**International
aspects**

Innovation

European Medicines Agency's mandate

The **European Medicines Agency's mandate** will be reinforced so that it can facilitate a coordinated Union-level response to health crises by:

- monitoring and mitigating the risk of shortages of critical medicines and medical devices
- Developing IT tool for monitoring and reporting of shortages of medicines
- Providing scientific advice on medicines which may have the potential to treat, prevent or diagnose the diseases causing those crises
- coordinating studies to monitor the effectiveness and safety of vaccines
- coordinating clinical trials.



Pharmaceutical Strategy for Europe

Flagship actions include:

- Evaluation of the basic pharmaceutical legislation
- Proposal of a European HERA agency
- Action to identify the vulnerabilities of the supply chains and actions to address them
- Develop cooperation between national authorities on pricing, payment and procurement policies.
- Creation of a robust digital infrastructure, including a European Health Data Space
- Support to research and innovation, notably via Horizon 2020
- Antimicrobials

Secure the supply of medicines across the EU and avoid shortages

- Flagship initiatives on open strategic autonomy
 - Propose to revise the pharmaceutical legislation
 - Follow up on the European Council request for open strategic autonomy and launch a structured dialogue with and between the actors in the pharmaceuticals manufacturing value chain and public authorities
 - Consider actions to ensure that the industry increases the transparency on the supply chains through voluntary process



“Future-proofing pharmaceutical legislation — study on medicine shortages”

Purpose of the study

- overview of medicines in shortage in the EU
- root cause analysis of shortages
- evidence-based assessment of the current framework (at EU and national level)
- potential solutions

Final Report 30 September 2021

Thank you



European Commission

Public Health information:

http://ec.europa.eu/health/index_en.htm

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https://ec.europa.eu/health/human-use/strategy_en

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Feedback mechanism: source: [ICF Analysis of contributions to the Roadmap](#)